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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/042,283	01/11/2002	Rymond C. Crippen	P 283269	4563
909	7590	10/16/2003		
PILLSBURY WINTHROP, LLP P.O. BOX 10500 MCLEAN, VA 22102				
			EXAMINER BRUNSMAN, DAVID M	
			ART UNIT 1755	PAPER NUMBER

DATE MAILED: 10/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding:

Office Action Summary	Application No. 10/042,283	Applicant(s) CRIPPEN ET AL.	
	Examiner David M Brunzman	Art Unit 1755	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4,6-9 and 15-49 is/are pending in the application.
- 4a) Of the above claim(s) 28-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4,6-9,15-27 and 34-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 28-33 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

Art Unit: 1755

Applicants' response including amendment and declaration filed 16 July 2003 have been carefully considered but, not found persuasive.

Newly submitted claims 28-33 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The originally presented claims so not include claims to a "kit" nor is there any basis in the originally filed disclosure for a "kit".

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 28-33 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 43-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The scope and meaning of the term "delivery system" is undefined. It is impossible to discern which limitations are imposed on these claims with recitation of the term "delivery system". The scope and meaning of the term "pre-dose" is unclear there is not definition of the term in the instant specification, in standard reference materials or any evidence of its meaning in the prior art of record, nor is any intrinsic meaning obvious. The scope and meaning of the term "designed for the prevention or delay of the onset of side effects" renders the scope of claim 48 unclear. The claim is directed to a "delivery system", it is unclear what limitations are introduced to a product claim by the state of mind of the inventor separate from those positively recited in the body of the claims.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1755

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4, 38, 39, 42, 43 and 45-49 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 04-096996.

The reference teaches a pelletized composition comprising calcium carbonate powder (limestone), activated carbon, and other nutrients (any nutrient would appear to help the body recover from consumption of alcohol by supporting the natural functions of the body consistent with the rules governing designation of a material as a dietary supplement). The differing intended use has not been shown to translate into an actual material difference in the product of the instant claims. The term “pellet” is indistinguishable from “tablet”.

Claims 43, 45, 47, 48 and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Sport-Horse Supreme.

The reference teaches a composition of calcium carbonate, activated carbon and B-vitamins.

Claims 4, 6, 7, 15, 16, 18-21, 24-27, 34 and 37-49 are rejected under 35 U.S.C. 102(b) as being anticipated by the ChaserTM publication.

The reference teaches a product for treatment of hangovers comprising caplets (capsule/tablets) each containing 325mg activated calcium carbonate (limestone), 175 mg activated carbon and 0.5mg Vitamin B2. The polysaccharides present in the caplet formulations are considered to be rehydration agents as they hold ambient moisture and no definition or example of “re-hydrating agents” is found in the instant specification.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8, 9, 23, 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over ChaserTM, as applied above.

The difference between the reference and instant claims 8, 9, 35 and 36 is the inclusion of pharmaceutical such as Olanzapine. The instant specification clearly indicates this compound is known for treatment of alcohol addiction. It would have been obvious to one of ordinary skill in the art to add a compound to treat alcohol addiction to a composition for treating symptoms of alcohol overuse because the consumers of Olanzapine would be expected to desire relief of their acute symptoms. The difference between the reference and claim 23 is the combination of treatment for alcohol abuse with administration of the instant product. It would have been obvious to one of ordinary skill in the art to treat alcohol addition in combination with administering a composition for treating symptoms of alcohol overuse because those undergoing addiction treatment would be expected to desire relief of their acute symptoms.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over ChaserTM, as applied above in view of the goaskalice.Columbia.edu article "Hangover-Helping Product".

The difference between the primary reference and the instant claims is the inclusion of Vitamin B-1 in the product. The Hangover-Helping Product article teaches that the effects of a hangover may be treated with Thiamin (B-1). It would have been obvious to one of ordinary

Art Unit: 1755

skill in the art to add Thiamin to the product of the primary reference because it is known in the art as effective to treat hangovers.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over ChaserTM, as applied above, in view of Grant et al.

The difference between the primary reference and the instant claims is the composition of the capsule itself. The primary reference does not disclose the encapsulating agent of the caplet therein. Grant et al, page 111, teaches that capsules for pharmaceutical use are commonly made of gelatin. It would have been obvious to one of ordinary skill in the art to employ a gelatin capsule because Grant et al teaches gelatin is effective for use thereas.

Applicants' response includes a declaration under rule 132 contradicting the office finding of public use as disclosed by the ChaserTM article. A single use in the public domain is sufficient to bar granting of a patent. *Egbert v. Lippmann*, 104 U.S. 333. Experimental use must be determined from an objective evaluation of the facts surrounding the transaction. *Allen Eng's Corp. v. Bartell Indus., Inc.* 63 USPQ2d 1769, quoting *EZ Dock v. Schafer., Inc.* 61 USPQ2d 1289. Once alleged experimental activity has been advanced by an applicant to explain a prima facie case under 35 U.S.C. 102(b), the examiner must determine whether the scope and length of the activity were reasonable in terms of the experimental purpose intended by applicant and the nature of the subject matter involved. MPEP 2133.03(e). No evidence supporting the allegations made by applicant in the declaration has been presented. Objective evidence should be presented by actual proof. MPEP 716.01.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M Brunsman whose telephone number is 703-308-3454. The examiner can normally be reached on M, W, F, Sa; 6:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Bell can be reached on 703-308-3823. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

David M Brunsman
Primary Examiner
Art Unit 1755



DMB